

REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on December 11, 2006. A Terminal Disclaimer is submitted herewith. The Director is authorized to charge \$130.00 for the Terminal Disclaimer and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112703-201 on the account statement.

Claims 8-20 are pending in this application. Claims 1-7 and 21-35 were previously withdrawn. In the Office Action, Claims 9, 11 and 13 are objected to for reasons of informality. Claims 8-20 are also provisionally rejected on the ground of non-statutory obviousness-type double patenting. Claims 8-20 are rejected on the ground of non-statutory obviousness-type double patenting. Claims 8-20 are rejected under 35 U.S.C. §103. In response Claims 9, 11 and 13 have been amended. The amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 9, 11 and 13 are objected to for reasons of informality. In response, the claims have been amended per suggestions from the Patent Office. Claim 9 has been amended to recite "nutraceuticals." Claim 11 has been amended to delete the word "ethyl maltol." Claim 13 has been amended to recite the phrase "selected" from the group consisting of. Accordingly, Applicants respectfully request that the objections to Claim 9, 11 and 13 be withdrawn.

In the Office Action, Claims 8-20 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 8-20 of co-pending U.S. Application No. 09/631,326. Submitted with this response is a Terminal Disclaimer disclaiming the terminal part of any patent granted on the pending application extending beyond the expiration date of any patent granted on the following U.S. Application No. 09/631,326.

Accordingly, Applicants respectfully request that the provisional rejection of Claims 8-20 under obviousness-type double patenting be withdrawn.

In the Office Action, Claims 8-20 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 1-11 of U.S. Patent No. 6,355,265 to Ream et al. ("*Ream*") in view of Claims 1-11 of U.S. Patent No. 6,060,078 to

Young Won Lee ("*Lee*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Independent Claims 8 and 16 recite, in part, a product comprising a medicament comprising a consumable tableted center and a coating comprising the medicament, the coating comprising at least 50% by weight of the product. In contrast, Applicants respectfully submit that there is no suggestion or motivation to combine *Ream* and *Lee* to obtain the present claims.

Applicants respectfully submit that one having ordinary skill in the art would not be motivated to combine *Ream* and *Lee* to arrive at the present claims. For example, Applicants respectfully submit that references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant." *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998) (quoting *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994)).

In its attempt to arrive at the present claims by combining the cited references, the Patent Office has ignored significant portions of each reference that teach away from the present invention. For example, *Ream* is entirely directed toward a chewing gum comprising a chewing gum center and a coating that surrounds the gum center. See, *Ream*, col. 6, lines 48-56. However, *Ream* does not disclose or even suggest the use of a consumable tableted center anywhere in the disclosure. In fact, unlike chewing gum, the consumable center of the present disclosure is "designed to dissolve in the mouth of the consumer and/or to be swallowed." See, Specification, page 9, lines 13-15. *Ream*, therefore, teaches away from the present invention, which requires, in part, the use of a consumable tableted center in a product comprising a medicament.

Similarly, *Lee* also teaches away from the present invention. *Lee* is entirely directed toward a tablet comprising a core containing a medicament in the center of the tablet and an outer layer wrapping the core. See, *Lee*, Abstract. However, *Lee* does not disclose or even suggest the use of a coating of a product where the coating comprises a medicament. In fact, *Lee* describes in detail the problems associated with tablets that do not contain the medicament in the

core. For example, tablets prepared in severe conditions, such as high temperatures, and containing medicaments that are unstable in the presence of high heat could suffer from a deterioration of the effects of the medicament if the medicament was transformed or evaporated during preparation of the tablet. See, *Lee*, Background of the Invention. In addition, placing the medicament portion of a tablet in the center of the tablet and surrounded by a coating lessens problems linked to the sandy and chalky taste that are sometimes associated with medicaments. *Id.* *Lee*, therefore, teaches away from the present invention, which requires, in part, the use of a coating of a product where the coating comprises a medicament. Because the cited references teach away from the claimed invention, the skilled artisan would have no reasonable expectation of success in combining the cited references to arrive at the present claims.

Moreover, the disclosures of *Ream* and *Lee* also teach away from a combination with each other. For example, *Lee* is directed toward a tablet comprising a core containing a medicament in the center of the tablet and an outer layer wrapping the core. See, *Lee*, Abstract. As previously discussed, *Lee* provides several reasons for including the medicament in the core of the tablet as opposed to the outer layer. These reasons include, generally, stability and taste of the tablet. See, *Lee*, col. 3, lines 25-61. In direct contrast, *Ream* is entirely directed toward a chewing gum product including a coating having a medicament. See, *Ream*, Abstract. By using a coated chewing gum product, *Ream* claims improved formulations where the medicament is released into the mouth and continued chewing creates a pressure in the buccal cavity forcing the medicament into the systemic system of the individual chewing the gum. See, *Ream*, col. 3, lines 17-25. Because both *Ream* and *Lee* list specific advantages to the placement of medicaments, and those advantages directly contradict each other, the cited references teach away from a combination with each other.

Applicants respectfully submit that what the Patent Office has done is to rely on a hindsight reconstruction of the claimed invention. It is only with a hindsight reconstruction of Applicants' claimed invention that the Patent Office is able to even attempt to piece together the teachings of the prior art so that the claimed invention is allegedly rendered obvious. Instead, the claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548 (Fed. Cir. 1983); 220 USPQ 303, 309 (Fed. Cir. 1983); *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995); 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). One should not use

hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d at 1075 (Fed. Cir. 1988).

In the Office Action, Claims 8-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Lee* in view of U.S. Patent No. 5,489,436 to Hoy et al. ("*Hoy*") and further in view of U.S. Patent No. 5,846,557 to Eisenstadt et al. ("*Eisenstadt*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Applicants respectfully submit that, even if combinable, all of the claimed elements are not taught or suggested by the cited references. For example, *Lee*, *Hoy* and *Eisenstadt* all fail to disclose or suggest a coating comprising a medicament as required, in part, by Claims 8 and 16. Instead, *Lee* is entirely directed toward a tablet comprising a core in the center of the tablet containing a medicament and an outer layer wrapping the core, as was previously discussed. See, *Lee*, col. 2, lines 1-3. Likewise, *Hoy* is entirely directed toward tablets wherein the active medicament is located in the core of the tablet and directly coated with a polymer blend to achieve a better balance between taste masking, dissolution and rate of bioavailability. See, *Hoy*, col. 2, lines 25-37. Similarly, *Eisenstadt* is entirely directed toward chewing gum compositions containing cough suppressing agents. See, *Eisenstadt*, col. 3, lines 62-67. In fact, none of the above-listed references even suggest a coating comprising a medicament as required, in part, by the present claims.

For at least the reasons discussed above, the combinations of *Lee*, *Hoy* and *Eisenstadt* fails to teach, suggest, or even disclose all of the elements of the present claims, and thus, fails to render the claimed subject matter obvious.

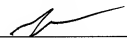
Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 8-20 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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